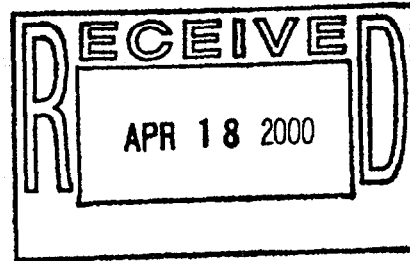


SB
SmithKline Beecham
Consumer Healthcare

70277

April 13, 2000

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204



Dear Sir/Madam,

In accordance with 21 CFR §101.93, SmithKline Beecham Consumer Healthcare, Pittsburgh PA 15230, is hereby giving notice that marketing has been initiated within the past 30 days for a dietary supplement that bears the following statement(s) on the label or in the labeling:

Statements: Refer to the attached labeling

Subject of Claims: Dietary ingredients Valerian Root Extract and Hops Extract

Name of Supplement: Alluna Sleep Herbal Supplement

The information contained in this notice is complete and accurate and SmithKline Beecham Consumer Healthcare has substantiation that the statements are truthful and not misleading.

If you have any questions pertaining to this notification, please contact me at (973) 889-2328.

Sincerely,

Patricia D. Wilson

Patricia D. Wilson
Regulatory Affairs Specialist

97S-0162

LET 5279



Alluna is a clinically tested formulation that promotes natural sleep. Its natural properties help promote calm and relaxation, so you can fall asleep naturally and rest through the night. Alluna helps your body maintain its own natural sleep pattern so you wake up refreshed. Alluna is safe to take over time. Unlike with many drugs, you should not experience lingering effects with this product after you wake up. Alluna is a special formulation of herbs that have been used for centuries. This formulation meets our modern, strict standards for safety and quality.

Supplement Facts

Amount Per % Daily Value	2 Tablets
Calories	5
Valerian Root Extract	500 mg †
Hops Extract	120 mg †
†Daily Value Not Established	

OTHER INGREDIENTS: microcrystalline cellulose, soy polysaccharide, hydrogenated castor oil, hydroxypropyl methylcellulose. Contains less than 2% of titanium dioxide, propylene glycol, magnesium stearate, silica, polyethylene glycol (400, 6,000 and 20,000), blue 2 lake, artificial flavoring.

SEE TOP OF BOX FOR DIRECTIONS.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Directions: Take two (2) tablets one hour before bedtime with a glass of water.

SEE PACKAGE INSERT FOR FURTHER INFORMATION ON HOW TO BEST USE ALLUNA AND TIPS ON SUPPORTING HEALTHY SLEEP HABITS.

Warning: As with all dietary supplements, contact your doctor before use if you are pregnant or lactating. Keep this and all dietary supplements out of the reach of children. Driving or operating machinery while using this product is not recommended. Chronic insomniacs should consult their doctor before using this product.

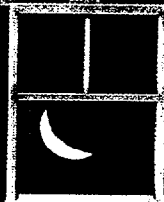
Please Note: The herbs in this product have a distinct natural aroma.

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A A

New!

Herbal Supplement

Alluna™ Sleep™



- Promotes a Healthy Sleep Pattern*
- Safe Natural Ingredients™
- Wake Up Refreshed*
- Not a Drug/Not Habit Forming

56 Tablets

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Tamper Evident Packaging. Tablets are sealed in blisters.
Do not use if seal is cut, torn, or broken.

Illustrations and overall packaging design elements are trademarked.

Store in a cool, dry place. Avoid temperatures above 86° F.

For more information on sleep, visit our web site at <http://www.alluna.com>

Comments or Questions?

Call Toll-Free 1-877-7ALLUNA Weekdays

Distributed by:
SmithKline Beecham
Consumer Healthcare, L.P.
Pittsburgh, PA 15230
Made in Switzerland
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28134XA



Package Insert—Please Read Carefully

Alluna Sleep

Herbal Supplement

Many people find that they cannot sleep at night because their minds are racing. They may be stressed, worried or anxious about details or events in their lives. Often these worries are temporary and normal, but they may disturb normal sleep patterns and habits for a very long time. Now, there's a new, natural product that can help. It's called Alluna Sleep.

Alluna is an approach to supporting healthy sleep that may be new for Americans. Yet, the basis for this natural herbal product has been in use for centuries in Europe. Alluna is a special, clinically tested valerian/hops combination formula that lets your body find its natural sleep pattern. Valerian and hops have been safely used by millions of people to promote restful sleep. Alluna helps you relax, so your body can fall asleep naturally.*

Alluna is a dietary supplement, and like other dietary supplements, it may take time to fully take effect. Depending on your body, you may feel relaxed the very first night you take Alluna or it may take a few evenings for your body to acclimate. Because of the gentle nature of the herbal combination, you can expect to wake up refreshed in the morning because you have experienced your natural sleep through the night. Therefore, you should not experience any "morning hangover" or grogginess. Alluna helps your body maintain a healthy sleep pattern to provide you with long-term, consistent results.*

Just as some dietary supplements are taken daily, Alluna should be taken nightly. Take **two** tablets one hour before bedtime with a glass of water. Depending on your particular circumstances, you should expect that over time your natural sleep patterns will be promoted and you may find that you no longer need to take Alluna.* You should listen to your body.

Alluna supplement's herbal ingredients are safe. Alluna is not a drug; it is a natural herbal supplement that helps to calm you so you can fall asleep naturally. Because Alluna helps promote natural sleep, the operation of a vehicle or heavy machinery is not advised.* Also, as with all dietary supplements, if you are pregnant or lactating, check with your doctor before taking Alluna. If you do not feel that your sleeping is improving after about a month, consult your doctor.

Alluna doesn't make you sleep. It lets you sleep.* ➡



Frequently Asked Questions About Alluna™

1. How does Alluna work? I mean, if it is not a drug, but promotes calmness, what is its mode of action? Modern scientists believe that valerian's mechanism of action is its ability to interact with certain receptors in your body. This can help you relax better. It should be noted that the active constituents of valerian appear to weakly interact with these receptors. While exhibiting an effect on the receptors, valerian has not been associated with dependence or any kind of physical addiction because it has no lingering effect.*

2. How long does Alluna stay in my body? Because the constituents of valerian weakly interact with these receptors, there is no lasting effect of valerian on the central nervous system. There is no residual effect that "lingers" in the body.*

3. Is Alluna habit forming? Alluna has no known addictive effects.

4. Is Alluna safe to take over a long period of time? Yes. Based on historical data, Alluna is well tolerated when used occasionally or intermittently for an unlimited period of time.

5. Can I take Alluna if I wake up in the middle of the night? Yes, but remember that Alluna is natural and its effect is not instantaneous. It helps you feel relaxed, and that calm state should help you to naturally drift off to sleep. Don't expect to be "knocked out."

6. Will I build up a tolerance to Alluna? Based on clinical evidence to date, no development of tolerance to Alluna's ingredients has been observed.

7. Will Alluna let me sleep through the whole night? Alluna has been shown to significantly promote a person's ability to stay asleep through the night. Again, it may take a few nights to reap the full benefits.* ➡



8. When will I notice a difference? You may notice a difference the first night you take **two** tablets of Alluna—you relax and fall asleep. However, the effect of Alluna may not be immediate. But you can expect it to work. Remember, when trying to promote your normal sleep pattern, patience is needed. Typically, the benefits of Alluna are seen after several days, with more consistent results after two weeks. To receive Alluna's full benefit, you may need to take it over a longer period.

9. Can I take Alluna any time of the day? Alluna is most effective when taken as directed to help promote natural sleep.* Take **two** tablets one hour before bedtime with a glass of water.

10. Can I chew an Alluna tablet? Alluna is purposely made as a small film-coated tablet because valerian is an herbal supplement with a taste and smell you may find unpleasant. It is recommended that you swallow the **two** tablets whole to ensure a pleasant experience.

11. If I take Alluna, will I still be able to wake up in the middle of the night if necessary (e.g., for an emergency)? Yes, you should not expect your sleep to be different from normal sleep patterns.*

12. Is it okay to take Alluna if I've had an alcoholic beverage? First of all, alcohol interferes with normal sleep patterns, and alcohol before bed will often disturb a regular night's sleep, making you feel groggy and literally "hung over" in the morning. Alluna does not exacerbate or accelerate alcohol's effects. However, if your goal is to return to a consistent good night's sleep, you should consider eliminating alcohol from your diet, especially right before retiring at night.

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Factors That Influence Sleep

There are many different factors that can influence both the quality and quantity of sleep. Some of these factors include:

Nighttime activities—Activities near bedtime that are physically, mentally, or emotionally stressful do not allow your body to get ready for restful sleep. You need a transition time between "active" and "sleepy." Also, caffeine, alcohol, smoking, and heavy meals can interfere with your body's sleep mechanisms.

Sleep habits—Engaging in the same routine at the same time every night signals your body that it is time to transition to sleep. Going to bed at different times can break that pattern. Getting up at different times in the morning can, too. Spending too much time awake in bed also can interfere with restful sleep, because the bed becomes associated with being awake.

Sleep environment—You probably know that bright lights, noise, and uncomfortable mattresses aren't good for sleeping. But when was the last time you really looked at where you sleep? A messy, cluttered room may interfere with relaxation. So can using your bedroom to do daytime work and chores such as paying your bills.

Sleep outlook—Worrying about sleep or pressuring yourself to sleep can keep you from sleeping.

At different times, your sleep may be influenced by any of these factors, and this may affect your performance the next day. It is important to try and promote a healthy, natural sleep pattern because this affects how well you sleep and ultimately, how well you function each day. Try new Alluna™ Sleep supplement. It's a healthy approach to promoting your natural sleep. ➔



Take Control of Your Sleep with Alluna™

If you are not sleeping well, take **two** Alluna Sleep tablets one hour before bedtime. Because Alluna is an herbal supplement, its effect is subtle. Some people feel its effects that first night. For others, it may take a few nights before the relaxing effects are felt.* The benefits of Alluna Sleep are fully realized if the product is taken regularly for a two-week period.

Sleep Tips

In addition to taking Alluna, you can also try some simple sleep tips that may help.

Nighttime Activities

- ⌋ Try to relax before bedtime. Remember, the natural properties of Alluna help your mind and body relax.* Try to stop work or other stressful activities at least one hour before bedtime.
- ⌋ Surprisingly, reading and watching TV in bed don't help you fall asleep naturally. Try to read or watch TV in another room.
- ⌋ Late night caffeine, heavy meals, and smoking disrupt sleep and, actually, so does alcohol. Try to avoid these a few hours before bedtime.

Bedtime Routine

- ⌋ Make your bedroom comfortable and calming (not too hot or too cold, comfortable bed, neat and uncluttered, quiet and dark).
- ⌋ Do the same things each night to get ready for sleep (changing to nightclothes, washing, checking doors and turning out lights).
- ⌋ Even though you should have a set bedtime, go to bed only when sleepy, not just fatigued, and get out of bed if sleep does not come within 30 minutes.

Outlook on Sleep

- ⌋ Think of sleep as a nighttime activity. Do not nap during the day.
- ⌋ Try not to worry about sleeping. Remind yourself of the positive steps you are taking to improve your sleep.
- ⌋ Don't watch the clock or try to force sleep; simply let Alluna and your body's natural rhythm make it happen.

Give yourself time. You didn't get to where you are in one night, so don't expect immediate benefits. Your body may need a few nights to work with the restful effects of Alluna. Give yourself time to replace your current sleep habits with sleep-inducing routines. Be patient with your body. ➔



*Congratulate yourself for taking steps to control your sleep patterns with the help of Alluna Sleep.**

In addition to Alluna Sleep, we offer you something extra—Alluna Healthy Sleep Matters.™

Please fill in the information below for Alluna Healthy Sleep Matters and a \$2.00 coupon good on your next purchase and mail to:

Alluna Healthy Sleep Matters, P.O. Box 3192, Grand Rapids, MN 55745-3192.

Comments or Questions? Call Toll-Free 1-877-7ALLUNA Weekdays

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SmithKline Beecham Consumer Healthcare, L.P.
Pittsburgh, PA 15230, Made in Switzerland

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Alluna, Alluna Healthy Sleep Matters healthcare information services, moon in window and house designs, and overall trade dress designs are trademarks/service marks of SmithKline Beecham Corporation.

CUT HERE

Name _____

Address _____

City _____ State _____ Zip _____

E-mail Address (Optional) _____

1. How often do you have difficulty sleeping? (Check one)
☐ More than once a week ☐ Once a week ☐ A few times a month
☐ Once a month ☐ A few times a year

2. How long have you had difficulty sleeping? (Check one)
☐ For weeks ☐ Months ☐ Years

3. Have you taken non-prescription sleep medication before?
☐ No ☐ Yes If so, what product? _____

4. Have you been prescribed a prescription sleep medication before?
☐ No ☐ Yes If so, what product? _____

5. What best describes your sleep problem? (Check one)
☐ Trouble falling asleep ☐ Waking during the night ☐ Waking too early

6. Where did you purchase Alluna™ Sleep? (Name the store) _____

SmithKline Beecham, the distributors of Alluna, will keep your information confidential. Your response will make you eligible to receive information or future promotional offers on Alluna or other SmithKline Beecham products.